

Remarks/Arguments:

With the present amendment, claims 2, 3, 9-11, and 18-24 are pending. Claims 22-24 have been withdrawn. No new matter has been added.

Claim rejections

Claim rejections under 35 U.S.C. §103

Caillouette in view of Bachynsky

Claim 18 stands rejected under 35 U.S.C. §103(a) as unpatentable over 5,651,372 to Caillouette ("Caillouette") in view of U.S. Patent No. 5,971,953 to Bachynsky (Bachynsky").

Claim 18 recites, *inter alia*, a device for needle biopsy adapted for aspiration of tissue specimens with a syringe cylinder, with a plunger displaceable therein as well as with a needle means. The needle means has at least one needle, whose channel opens into the interior of the cylinder. A ventilation means is formed by at least one overflow channel, which is formed at a distance from the syringe bottom in the inner wall of the cylinder. The length of the channel in the direction of the cylinder axis makes it possible that the volume between the bottom and the plunger can be temporarily connected with the interior of the cylinder that is located above the plunger via at least one overflow channel.

Caillouette discloses a biopsy syringe having a barrel 10 with a movable plunger 12. A side wall of barrel 10 includes an aperture 20. Caillouette, Col. 2, lines 28-29, 49-50. Aperture 20 vents air into barrel 10 when plunger 12 is withdrawn to a position behind aperture 20. *Id.*, Col. 2, lines 63-65.

Bachynsky discloses a dual chamber syringe apparatus for dispensing a dry medicine that is to be reconstituted just prior to administration to a patient. Bachynsky, Abstract, lines 1-2. The apparatus includes a syringe barrel 11 having an upper chamber 20 for containing a fluid and a lower chamber 22 containing a dry medicine or drug 24. Bachynsky, Col. 7, lines 8-12. An enlarged diameter section 25 extends between upper chamber 20 and lower chamber 22 (FIG. 1) and includes a cylindrical wall 26 and a plurality of radially and longitudinally extending ribs 29. Bachynsky, Col. 7, lines 13-19. Each pair of ribs defines therebetween a bypass flow channel 30. *Id.*, Col. 7, lines 22-23. During use, when a lower piston 32 is disposed within enlarged diameter section 25, liquid diluent in upper chamber 20 flows via channels 30 into lower chamber 22 where the liquid mixes with a dry drug. *Id.*, Col. 7, lines 20-27.

Bachynsky further discloses a hydrophobic membrane at lower piston 32. *Id.*, Col. 5, lines 11-13. Lower piston 32 includes a central opening that aligns with an opening 37 through a tubular member 36 attached to lower piston 32. *Id.*, Col. 7, lines 55-58 and FIG. 6. Tubular member 36 telescopes within bore 41 of a plunger 40. *Id.*, Col. 7, lines 60-61. A vent opening 44 in plunger 40 allows air to escape through membrane 39, opening 37, and opening 44 into surrounding atmosphere. *Id.*, Col. 8, lines 6-10.

The Office Action alleges that Bachynsky teaches a ventilation means formed by at least one overflow channel. Office Action, page 5, lines 5-6. The Office Action also alleges that it would have been obvious to a person having ordinary skill in the art to modify the device taught by Caillouette by substituting the piston bypass means disclosed by Caillouette for the piston bypass means taught by Bachynsky in order to release a vacuum from the syringe once an adequate sample has been obtained and allows for the sample to be withdrawn while the sample is in the needle. *Id.*, lines 16-21.

Applicants respectfully traverse this rejection. Regarding the allegation that Bachynsky teaches a ventilation means formed by at least one overflow channel, Applicants respectfully submit that Bachynsky does not disclose enlarged diameter section 25 with a plurality of overflow channels *as a ventilation means*. To the contrary, Bachynsky discloses enlarged diameter section 25 as allowing liquid to flow *from upper chamber 20 into lower chamber 22 to mix pharmaceuticals*. Bachynsky, Col. 5, lines 14-19 and Col. 7, lines 13-27. Further, Bachynsky does disclose a ventilation means as membrane 39 covering opening 37 in tubular member 36 and plunger bore 41 in plunger 40 that allows any air contained in lower chamber 22 to escape through membrane 39, opening 34, and opening 37. *See* Bachynsky, Col. 7, line 64 - Col. 8, line 12 and FIG. 6.

In attempting to combine the teaching of Caillouette with the teaching of Bachynsky, the Office Action ignores the requirement in Bachynsky that venting of lower chamber 22 be performed through opening 37 in tubular member 36 and plunger bore 41 in plunger 40. As stated in M.P.E.P. §2141.02 VI, however, "[a] prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 202 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)."

Because, in accordance with M.P.E.P. §2141.02 VI, Bachynsky must be considered in its entirety, a person of ordinary skill in the art, having Bachynsky in front of him and seeking to modify Caillouette with the teaching of Bachynsky to vent the biopsy syringe of Caillouette,

would understand that such modification would be directed to modifying the plunger, and not the syringe body, as suggested by the Office Action.

Further, "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d 238 at 241, 147 USPQ 391 at 393 (CCPA 1965). As discussed above, Bachynsky clearly states that the enlarged section of the syringe wall is "to facilitate thorough mixing of all pharmaceuticals" (Bachynsky, Col. 5, lines 16-19), while the ventilation suggestion is provided by membrane 39, opening 37 in tubular member 36, and vent opening 44 in plunger 40.

Applicants respectfully submit that a person having ordinary skill in the art would appreciate enlarged diameter section 25 to facilitate mixing of wet and dry pharmaceuticals (*Id*), and not to break a vacuum during the withdrawal of the plunger, as suggested by the Office Action.

Because the proposed combination of Caillouette with Bachynsky is improper, Applicants respectfully submit that the Office Action fails to establish a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claim 18.

Caillouette in view of Bachynsky and Chin

Claims 2, 3, and 19 stand rejected under 35 U.S.C. §103 as unpatentable over Caillouette in view of Bachynsky and U.S. Patent No. 5,971,953 to Chin et al. ("Chin"). Claims 2, 3, and 19 ultimately depend from claim 18. Chin is cited for allegedly disclosing a device with a stop means that limits the depth of penetration of the needle into the body. The proposed combination of Caillouette with Bachynsky and Chin fails to make up the deficiencies of Caillouette and Bachynsky with respect to claim 18. Namely, Chin fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Caillouette with Bachynsky and Chin fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claims 2, 3, and 19.

Caillouette in view of Bachynsky and Rieck

Claim 9 stands rejected under 35 U.S.C. §103 as unpatentable over Caillouette in view of Bachynsky and U.S. Patent No. 2,551,902 to Rieck ("Rieck"). Claim 9 depends from claim 18. Rieck is cited for allegedly disclosing a device comprising a common projection sleeve that can be attached by plugging to the syringe cylinder over the needles. The proposed combination of Caillouette with Bachynsky and Rieck fails to make up the deficiencies of Caillouette and Bachynsky with respect to claim 18. Namely, Rieck fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Caillouette with Bachynsky and Rieck fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claim 9.

Caillouette in view of Bachynsky Dejter, Jr.

Claims 10 and 11 stand rejected under 35 U.S.C. §103 as unpatentable over Caillouette in view of Bachynsky and U.S. Patent No. 5,060,658 to Dejter, Jr. et al. ("Dejter"). Claims 10 and 11 ultimately depend from claim 18. Dejter is cited for allegedly disclosing a device with a filter means that is arranged in a path between the opening of channels into the tips of each of the at least one needle and the interior of the syringe cylinder, wherein the filter means comprises individual filter inserts in the tip-side end area of the at least one needle. The proposed combination of Bachynsky with Gibbs and Dejter fails to make up the deficiencies of Bachynsky with respect to claim 18. Namely, Dejter fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Bachynsky with Gibbs and Dejter fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claims 10 and 11.

Caillouette in view of Bachynsky and Ferguson

Claim 20 stands rejected under 35 U.S.C. §103 as unpatentable over Caillouette in view of Bachynsky and U.S. Patent No. 6,972,006 and U.S. Patent Application Publication No. US2004/0054332, both to Ferguson ("Ferguson"). Claim 20 depends from claim 18. Ferguson is cited for allegedly disclosing at least one indicator projection that projects from the inner wall

of the cylinder. The proposed combination of Caillouette with Bachynsky with Ferguson fails to make up the deficiencies of Caillouette and Bachynsky with respect to claim 18. Namely, Ferguson fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Caillouette and Bachynsky with Ferguson fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claim 20.

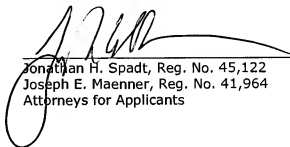
Caillouette and n view of Bachynsky and Schwarz

Claim 21 stands rejected under 35 U.S.C. §103 as unpatentable over Caillouette and n view of Bachynsky and DE-20212639 to Schwarz ("Schwarz"). Claim 21 depends from claim 18. Schwarz is cited for allegedly disclosing a syringe device having a plurality of needles having different lengths. The proposed combination of Caillouette with Bachynsky and Schwarz fails to make up the deficiencies of Caillouette and Bachynsky with respect to claim 18. Namely, Schwarz fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Schwarz with Caillouette and Bachynsky fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claim 21.

Conclusion

In light of the above remarks, Applicants respectfully submit that the present application is in condition for allowance. Applicants respectfully request prompt consideration and allowance of the claims.

Respectfully submitted,



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